

110TH CONGRESS
2^D SESSION

S. 1382

AN ACT

To amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “ALS Registry Act”.

3 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
4 **ACT.**

5 Part P of title III of the Public Health Service Act
6 (42 U.S.C. 280g et seq.) is amended by adding at the end
7 the following:

8 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REG-**
9 **ISTRY.**

10 “(a) ESTABLISHMENT.—

11 “(1) IN GENERAL.—Not later than 1 year after
12 the receipt of the report described in subsection
13 (b)(2)(A), the Secretary, acting through the Director
14 of the Centers for Disease Control and Prevention,
15 may, if scientifically advisable—

16 “(A) develop a system to collect data on
17 amyotrophic lateral sclerosis (referred to in this
18 section as ‘ALS’) and other motor neuron dis-
19 orders that can be confused with ALS,
20 misdiagnosed as ALS, and in some cases
21 progress to ALS, including information with re-
22 spect to the incidence and prevalence of the dis-
23 ease in the United States; and

24 “(B) establish a national registry for the
25 collection and storage of such data to develop a
26 population-based registry of cases in the United

1 States of ALS and other motor neuron dis-
2 orders that can be confused with ALS,
3 misdiagnosed as ALS, and in some cases
4 progress to ALS.

5 “(2) PURPOSE.—It is the purpose of the reg-
6 istry established under paragraph (1)(B) to—

7 “(A) better describe the incidence and
8 prevalence of ALS in the United States;

9 “(B) examine appropriate factors, such as
10 environmental and occupational, that may be
11 associated with the disease;

12 “(C) better outline key demographic fac-
13 tors (such as age, race or ethnicity, gender, and
14 family history of individuals who are diagnosed
15 with the disease) associated with the disease;

16 “(D) better examine the connection be-
17 tween ALS and other motor neuron disorders
18 that can be confused with ALS, misdiagnosed
19 as ALS, and in some cases progress to ALS;
20 and

21 “(E) other matters as recommended by the
22 Advisory Committee established under sub-
23 section (b).

24 “(b) ADVISORY COMMITTEE.—

“(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ‘Advisory Committee’). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

“(A) two-thirds of such members shall represent governmental agencies—

“(i) including at least one member representing—

“(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

“(II) the Department of Veterans Affairs;

1 “(III) the Agency for Toxic Sub-
2 stances and Disease Registry; and

3 “(IV) the Centers for Disease
4 Control and Prevention; and

5 “(ii) of which at least one such mem-
6 ber shall be a clinician with expertise on
7 ALS and related diseases, an epidemiolo-
8 gist with experience in data registries, a
9 statistician, an ethicist, and a privacy ex-
10 pert (relating to the privacy regulations
11 under the Health Insurance Portability
12 and Accountability Act of 1996); and

13 “(B) one-third of such members shall be
14 public members, including at least one member
15 representing—

16 “(i) national and voluntary health as-
17 sociations;

18 “(ii) patients with ALS or their fam-
19 ily members;

20 “(iii) clinicians with expertise on ALS
21 and related diseases;

22 “(iv) epidemiologists with experience
23 in data registries;

1 “(v) geneticists or experts in genetics
2 who have experience with the genetics of
3 ALS or other neurological diseases and

4 “(vi) other individuals with an interest
5 in developing and maintaining the National
6 ALS Registry.

7 “(2) DUTIES.—The Advisory Committee may
8 review information and make recommendations to
9 the Secretary concerning—

10 “(A) the development and maintenance of
11 the National ALS Registry;

12 “(B) the type of information to be col-
13 lected and stored in the Registry;

14 “(C) the manner in which such data is to
15 be collected;

16 “(D) the use and availability of such data
17 including guidelines for such use; and

18 “(E) the collection of information about
19 diseases and disorders that primarily affect
20 motor neurons that are considered essential to
21 furthering the study and cure of ALS.

22 “(3) REPORT.—Not later than 270 days after
23 the date on which the Advisory Committee is estab-
24 lished, the Advisory Committee may submit a report
25 to the Secretary concerning the review conducted

1 under paragraph (2) that contains the recommenda-
2 tions of the Advisory Committee with respect to the
3 results of such review.

4 “(c) GRANTS.—The Secretary, acting through the
5 Director of the Centers for Disease Control and Preven-
6 tion, may award grants to, and enter into contracts and
7 cooperative agreements with, public or private nonprofit
8 entities for the collection, analysis, and reporting of data
9 on ALS and other motor neuron disorders that can be con-
10 fused with ALS, misdiagnosed as ALS, and in some cases
11 progress to ALS after receiving the report under sub-
12 section (b)(3).

13 “(d) COORDINATION WITH STATE, LOCAL, AND FED-
14 ERAL REGISTRIES.—

15 “(1) IN GENERAL.—In establishing the Na-
16 tional ALS Registry under subsection (a), the Sec-
17 retary, acting through the Director of the Centers
18 for Disease Control and Prevention, may—

19 “(A) identify, build upon, expand, and co-
20 ordinate among existing data and surveillance
21 systems, surveys, registries, and other Federal
22 public health and environmental infrastructure
23 wherever possible, which may include—

1 “(i) any registry pilot projects pre-
2 viously supported by the Centers for Dis-
3 ease Control and Prevention;

4 “(ii) the Department of Veterans Af-
5 fairs ALS Registry;

6 “(iii) the DNA and Cell Line Reposi-
7 tory of the National Institute of Neuro-
8 logical Disorders and Stroke Human Ge-
9 netics Resource Center at the National In-
10 stitutes of Health;

11 “(iv) Agency for Toxic Substances
12 and Disease Registry studies, including
13 studies conducted in Illinois, Missouri, El
14 Paso and San Antonio, Texas, and Massa-
15 chusetts;

16 “(v) State-based ALS registries;

17 “(vi) the National Vital Statistics Sys-
18 tem; and

19 “(vii) any other existing or relevant
20 databases that collect or maintain informa-
21 tion on those motor neuron diseases rec-
22 ommended by the Advisory Committee es-
23 tablished in subsection (b); and

24 “(B) provide for research access to ALS
25 data as recommended by the Advisory Com-

1 mittee established in subsection (b) to the ex-
2 tent permitted by applicable statutes and regu-
3 lations and in a manner that protects personal
4 privacy consistent with applicable privacy stat-
5 utes and regulations.

6 “(2) COORDINATION WITH NIH AND DEPART-
7 MENT OF VETERANS AFFAIRS.—Consistent with ap-
8 plicable privacy statutes and regulations, the Sec-
9 retary may ensure that epidemiological and other
10 types of information obtained under subsection (a) is
11 made available to the National Institutes of Health
12 and the Department of Veterans Affairs.

13 “(e) DEFINITION.—For the purposes of this section,
14 the term ‘national voluntary health association’ means a
15 national non-profit organization with chapters or other af-
16 filiated organizations in States throughout the United
17 States with experience serving the population of individ-
18 uals with ALS and have demonstrated experience in ALS
19 research, care, and patient services.”.

20 **SEC. 3. REPORT ON REGISTRIES.**

21 Not later than 18 months after the date of enactment
22 of this Act, the Secretary of Health and Human Services
23 may submit to the appropriate committees of Congress a
24 report outlining—

25 (1) the registries currently under way;

- 1 (2) future planned registries;
- 2 (3) the criteria involved in determining what
- 3 registries to conduct, defer, or suspend; and
- 4 (4) the scope of those registries.
- 5 The report may also include a description of the activities
- 6 the Secretary undertakes to establish partnerships with re-
- 7 search and patient advocacy communities to expand reg-
- 8 istries.

Passed the Senate September 23 (legislative day,
September 17), 2008.

Attest:

Secretary.

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